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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,755

08/20/2003

Timothy R. MacHold

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8052

24201 7590 11/05/2009
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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

11/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,755	Applicant(s) MACHOLD ET AL.	
	Examiner ROBERT L. NASSER	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/21/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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The examiner notes that the current claims do not find support in 09/563946 or 60/185561. Therefore, the filing date of the current claims is that of 09/707257, or 11/9/2000.

Applicant has stated that the priority documents support the current claims. In support of this assertion, applicant noted that the device of the priority document uses a TE cooler/heater which has a warm up or ramp up period to the desired temperature and during that period, the temperature of the heater/cooler will change and the heat exchange rate will change. While this may be true, the claim recites that the controller varies the rate of heat exchange (addition or removal) as a function of the temperature differential between the current body temperature and the target temperature. This feature is not disclosed in the priority documents. Accordingly, it is the examiner's position that the claims are not supported by the priority documents.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 30-34 and 36-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Ginsburg WO 00/10494. On page 34, lines 17-20, Ginsburg discuss a control scheme for a heat exchange catheter where the heat transfer

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rate from the catheter to the blood is tapered as the temperature approaches the target temperature. As such, it has a method of providing the heat transfer catheter with a heat transfer region, sensing body temperature, measuring the catheter heat transfer temperature (see pages 32-33), providing a controller, i.e. a microprocessor, to heat the blood, selecting a target temperature, and selecting a heat exchange right initially, which also selects a ramp rate. As the body temperature approaches the target temperature, i.e. is below a predetermined threshold, a different heat exchange and hence ramp rate is chosen. Claims 31 and 32 are rejected in that the catheter has a circulating fluid and the temperature of the heat transfer region is set by setting the fluid temperature. Accordingly, the temperature of the region is sensed by sensing the fluid temperature. In addition, on page 32, Ginsburg discussed adjusting the catheter and hence fluid temperature based on the target temperature. In addition, the operator can manually control the system. As to claim 37, Ginsburg sets an initial rate and catheter temperature, and inherently adjusts the rate of heat addition/removal to maintain the desired rate.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg et al. The exact sample right would have been a mere matter of design choice for one skilled in the art

Applicant's arguments filed 7/17/2009 have been fully considered but they are not persuasive.

Applicant has argued that Ginsburg is not available as a reference because the priority documents support the current claims. As noted above, it is the examiner's position that the claims are not supported. Hence, there is no support for the claimed subject matter in the parent application and the claims stand with the filing date of 09/707257, or 11/9/2000. As such, Ginsburg is still a reference against the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
November 3, 2009